

REMARKS

In the Office action, the Examiner takes the position that the present application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with this position, the Examiner is requiring the Applicants to elect a single invention to which the claims must be restricted. The groups of inventions identified by the Examiner in the Office action are as follows:

Group I, claims 1-10, 13 and 15 drawn to a polypeptide and a pharmaceutical composition comprising a polypeptide.

Group II, claims 11, 12, drawn to a method of diagnosing prion diseases

Group III, claim 14, drawn to a DNA molecule encoding a polypeptide.

Group IV, claim 16, drawn to a DNA molecule encoding a polypeptide.

Group V, claim 17 drawn to a method of detecting PrPSc specific surface sequence zones.

Group VI, claim 18, drawn to a method of screening a library.

In addition to the foregoing, the Examiner states that: "The inventions are also distinct, each from the other because of the following reasons: Claims 2, 3, 6 and 13 encompass more than one distinct amino acid sequences with different corresponding primary structures. The proteins are structurally different; therefore, the applicant must elect a specific sequence for examination."

In telephone conversations with the undersigned attorney on May 2, the Examiner and her Supervisory Examiner, agreed to combine Groups I and II for purposes of election.

The Applicants hereby elect, with traverse, Groups I & II and SEQ ID NO. 2 with the following specific sequence:

Tyr-Tyr-Lys-Pro-Met-Asp-Arg-Tyr-Asn

The foregoing specific sequence is covered by SEQ ID NO. 2. As set forth in the present application, the first two positions and the last two positions of the sequence can be absent. In addition, position 5 can be occupied by **Lys**, position 7 can be occupied by **Met**, position 9 by **Arg** and position 11 by **Asn**. All of the claims, except claim 3 read on the elected sequence.

The Applicants traverse the Examiner's restriction requirement and hereby request reconsideration of the Examiner's restriction requirement for the following set forth below.

Initially, it is noted that unity of invention was implicitly acknowledged during the international phase. Accordingly, it is submitted that under Article 27 of the PCT and 37 CFR.1475, the USPTO cannot now properly require restriction.

According to PCT Rules 13.1 and 13.2, the unity requirement is met if a group of inventions is linked so as to form a general inventive concept, i.e., that there is a technical relationship among the inventions. The inventions have to share one or more of the same or corresponding **special technical features**. The expression "**special technical features**" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The Examiner ostensibly bases the restriction requirement of Groups I-VI, on the Examiner's opinion that claim 1 is not novel and that PCT Rules 13.1 - 13.2 do not allow for multiple products and processes. Applicants will address the issue of novelty of claim 1 in their response to the first substantive Office action on the merits. With regard to the Examiner's assertion that PCT Rules 13.1 and 13.2 do not allow for multiple products and processes, Applicants respectfully submit that this is incorrect. At best, 37 CFR §1.475 (which corresponds to PCT Rule 13 states (with emphasis added) "If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention *might not* be present." This language, however, is clearly not mandatory.

Applicants submit that there is unity of invention between Groups I-VI because they share one or more of the same or corresponding special technical features, namely they are all defined sequences of PrP, or sequences derived therefrom, that are recognized by PrP^{Sc} binding substances.

With regard to claim 14, applicants would also like to specifically point out that in the MPEP (Appendix Administrative Instructions Under the PCT, Instructions

Concerning Unity of Invention, §II Claims in Different Category, Example 17, Claim 1), an example is given wherein there is unity of invention between Claim 1 reciting a Protein X and Claim 2 reciting a DNA sequence encoding protein X. The MPEP states: "Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted."

Based on the foregoing, Applicants submit that there is unity of invention with regard to Groups I-VI.

With regard to the amino acid sequences recited in claims 2, 3 and 6, Applicants submit that there is unity of invention because they share one or more of the same or corresponding special technical features, namely they are all defined sequences of PrP, or sequences derived therefrom, that are recognized by one of the following PrP^{Sc} binding substances: specific antigen denoted by 15B3, recombinant bovine rbPrp, and Congo Red dye.

As grounds for requiring an election of one of the specific species, the Examiner states that the "proteins are structurally different". According to MPEP §1850, however, a lack of structural similarity is not fatal to a finding of unity. According to the Markush Practice section of MPEP §1850, unity of invention will be found in such cases where all alternatives belong to a recognized class of chemical compounds. In claims 2, 3 and 6, all of the sequences are synthetic polypeptides that are defined sequences of PrP, or sequences derived therefrom, that are recognized by one of the following PrP^{Sc} binding substances: specific antigen denoted by 15B3, recombinant bovine rbPrp, and Congo Red dye.

With regard to the requirement to identify a specific sequence within a sequence number (i.e., identify the specific R groups), Applicants submit that there is common structure present, hence their ability to be represented by a formula. Moreover, the Markush Practice section of the MPEP §1850 states that the "structural element may be a single component or a combination of individual components linked together".

In making the election requirement with regard to the sequences, the Examiner repeatedly states that the inventions are "distinct". Moreover, the Examiner uses a slightly modified version of the paragraph used in Section 8.01 "Election of Species" of MPEP §809.02 to require the Applicants to list all claims readable on the sequence. Applicants submit that Section 8.01 and the concept of "distinct" Inventions has no place in a unity of invention determination. Thus, Applicants submit that although the Examiner has cited the PCT Rules, it appears the Examiner is not applying the appropriate standard in determining unity of invention.

Based on the foregoing, Applicants submit that there is unity of invention with regard to claims 2, 3, 6 and 13.

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Respectfully submitted,

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